REMARKS

The Office has pointed out an inconsistency in the inventors' declaration submitted in this application. Applicants are submitting concurrent with this response a new inventors' declaration which corrects the filing date of provisional application serial no. 60/464,645 and adds the additional priority application provisional application serial no. 60/470,420, filed May 15, 2003.

Claims 1, 3-6, 10-14 and 17-18 are rejected as not supported by adequate written description. Applicants have amended independent claim 1 to specify the feature that the thymosin alpha peptide is selected from naturally occurring thymosin alpha 1 or synthetic or recombinant thymosin alpha 1 having substantially the same squence. Claims 15 and 19 are cancled as redundant in view of the amendment to claim 1. This amendment is supported in the original specification at paragraph 13 and contains no new matter. Applicants submit that the skilled reader would readily accept that the inventors possessed these thymosin alpha 1 peptides and the methods claimed using them. Applicants therefore request withdrawal of the rejection.

Claims 1 and 3-19 are rejected as not enabled. Applicants are required to describe the claimed invention in such a manner that the skilled person would have been able to make and use the invention in its full scope without undue experimentation. The Office Action has divided the discussion according to Wands factors for determining whether experimentation is undue, but does not specifically state why the skilled reader would require any experimentation to treat or prevent respiratory coronavirus infection or what experimentation assertedly would be required. Applicants request withdrawal of the invention for this reason alone.

The factors cited by the Office as evidencing lack of enablement include the fact that the claims recite prevention of infection. The Office has not presented any evidence whatsoever, however, showing that prevention of disease as discussed in the specification at paragraph 12 according to the administration and dosage regimens

described could not be practiced by a skilled worker to prevent infection. Paragraph 12 states that administration for prevention relates to persons at high risk due to contact with suspected disease carriers or to asymptomatic carriers, not to all people everywhere as the Office Action implies. The Office has not explained why "prevent" is being interpreted here according to a narrow definition to mean "totally prevent" all disease everywhere, i.e. complete irradiation of disease, when that is not recited in the claims or required by the description in the specification. The claims do not recite that the condition is "totally prevented." Therefore, Applicants submit that this interpretation is not proper.

The Office impliedly criticizes the invention because the prior art has not yet developed a treatment consensus for SARS. Applicants submit that this does not relate to whether SARS treatment is unpredictable, since the disease is of fairly recent origin.

The claims are considered broad with respect to the compounds for treatment (see page 9, lines 17-21 of the Action). Applicants have amended the claims with respect to this feature and submit that this factor no longer militates against Applicants here, even if taken as true.

The Action notes that no working examples are included. The specification provides detailed guidance concerning the treatment method, for example in terms of duration, dose, time and method of administration and so forth. Applicants submit that this guidance is sufficient to enable practice of the invention in its full scope. The Office points again to the assertedly broadly claimed TA1 derivatives. Applicants have amended this aspect of the claims here. The Action also mentions that the reader would be burdened with undue experimentation to determine if the peptides claimed could be used. Applicants have amended the language concerning the claimed peptides and submit now that there is no reason why one would need to (or even expect to need to) perform any more than routine testing to practice the invention claimed herein.

The Office then asserts that a great deal of experimentation would be required concerning how to use the invention. The specification gives a great deal of guidance

concerning how to administer the claimed compounds to treat or prevent SARS, a respiratory coronavirus. The Action does not indicate what experiments would be required, how much experimentation would be needed, or why this would be undue; it merely states that the amount of this (unspecified) experimentation would be undue. Applicants submit that the Office has not presented any reasons why this factor initiates against Applicants.

In summary, the Office points to an unsubstantiated narrow definition of a claim term, the fact that the invention has not yet been made prior to the present invention, breadth of claims which are amended herein, and lack of working examples when detailed guidance concerning practice of the invention is present in the specification, in order to conclude that required experimentation would be undue. Applicants submit that the practitioner would be able to read this specification and, guided also by the knowledge of one of skill in this art (which the Office concedes is high), be able to administer the claimed peptides to treat or prevent respiratory coronavirus infection as discussed in the application.

Furthermore, clinical practitioners are accustomed to adjust dosages and treatment regimens. Therefore, the amount of experimentation which would be considered "undue" in this art is high. Applicants submit that the guidance provided here is more than sufficient to allow a skilled physician to treat or prevent coronavirus infection according to the claimed method. Applicants therefore request that this rejection be withdrawn.

Claims 1, 3-12 and 17 are rejected as anticipated by Sherman et al. (Hepatology 27:1128-1135, 1998; hereinafter "Sherman"). Sherman is dated in 1998 by the Office. This reference relates to thymosin alpha 1 as a treatment for hepatitis C and was evidently written far prior to the first report of SARS, a new disease first recognized in 2003 (see specification, paragraph 3).

Applicants submit that Sherman does not teach any method expressly for treatment of any respiratory coronavirus or SARS in particular. The Office apparently is relying on an asserted inherent anticipation of the claimed methods because the

hepatitis C patients of Sherman did not have SARS and therefore were candidates for prevention of this disease. The specification describes the methods, when used for prevention, to relate "to persons at high risk because of contact with suspected disease carriers, or in carriers who are asymptomatic." See paragraph 12. Applicants submit that it would not have been possible in 1998 that the patients described in Sherman met this definition since SARS did not exist at that time and therefore the patients could not have had contact with or been carriers of SARS. The disclosures of Sherman cannot inherently anticipate or render obvious any coronavirus treatment since it does not even mention such treatments and the Office Action has not cited any disclosure even remotely related to SARS. In order for a reference to anticipate a patent claim, the reference must disclose, expressly or inherently, each and every element of the claim. Sherman cannot do this for the reasons discussed above. Applicants request withdrawal of the rejection.

Claims 1, 3-9, 13, and 17-18 are provisionally rejected on grounds of non-statutory double patenting over claims of co-pending application serial no. 10/535,835. Claims 1 and 3-6 are provisionally rejected over claims of co-pending application serial nos. 11/577,645 and 11/558,281. Applicants would like to point out that each of these three cited applications were filed after the present application.

Serial no. 10/535,835 claims a method for treating radiation damage. Nothing in these claims even relates to a coronavirus treatment. Applicants submit that these claims are not even related to the same subject matter and do not render obvious the invention claimed here. Serial no. 11/577,645 relates to and claims a treatment for hemmorhagic viral infection using a chemical compound according to a generic chemical formula that contains a gamma-glutamyl dipeptide moiety. Thymosin alpha 1 does not contain such a moiety, and moreover the claims do not even refer to SARS or respiratory coronaviruses. This application also cannot render obvious the claims presented here. Serial no. 11/558,281 claims a method for treatment or prevention of a respiratory viral infection, but the claims recite a compound according to a generic chemical formula that contains a gamma-glutamyl moiety and therefore does not

encompass thymosin alpha 1. The claims do not mention or suggest any use of thymosin alpha 1 and therefore cannot render obvious the method claimed here.

Applicants request withdrawal of the provisional double patenting rejections.

Applicants request reconsideration of the claims and allowance of the application at this time.

The response is timely. The Office is authorized to charge any fees deemed necessary in connection with this response to Deposit Account 02-2135.

Respectfully submitted,

By: _____

Martha Cassidy
Attorney for Applicants
Registration No. 44,066
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202)783-6040